

REMARKS

Currently, claims 23-36 remain pending in the present application, including independent claim 23. As shown above, independent claim 23 has been amended to clarify that the quaternary amine acrylate polymer is a quaternary amine acrylate hydrogel polymer.

The Office Action rejected independent claim 23 under 35 U.S.C. §103 in view of U.S. Pat. No. 6, 287,285 to Michal, et al. As discussed in detail in Applicants' previous response of March 27, 2006, Michal, et al. describes two different embodiments of methods of coating a medical device with a hydrophilic agent that is lubricious against biological tissue. The hydrophilic coating is bound to the device surface due to the grafting component used alone or in combination with the binding component. Col. 5, ll. 48-53. However, Michal, et al. fails to disclose or suggest a lubricious coating comprising a quaternary amine acrylate hydrogel polymer that has been cross-linked to a multi-functional monomer, as required by independent claim 23.

In fact, referring to the attached Decision on Appeal in the present application's parent application serial no. 10/325,443, the Board of Patent Appeals and Interferences (Administrative Patent Judges Warren, Timm, and Smith) states that:

“The sole applicable disclosure of “2-aminoethyl methacrylate” in Michal ‘285 is with respect to the embodiment at col. 7, l. 57, to col. 8, l. 13, particularly, col. 8, l. 2. In this disclosure, the material is described as “a (co)monomer” for a hydrophilic agent top coat. However, this is in the context of “the binding component comprises an aldehyde compound and the top coat is a compound having amine groups” (col. 7, ll. 57-59). We find that one of ordinary skill in this art would have recognized from this embodiment that the reaction of the amine and aldehyde functional groups would result in imine moieties, as is well known in the organic chemistry arts, which moieties in the disclosure of Michal ‘285 crosslink the binding component and the polymeric top coat (see also col. 6, l. 65, to col. 7, l. 3).

Thus, even if a number of amino groups remain unreacted in the polymeric top coat and may be protonated as the examiner finds, there is no showing on this record that the same would result in a hydrogel

polymer and certainly not a hydrogel quaternary amine acrylate polymer..." Pg. 7, lines 11-23.

Applicants recognize that the Examiner in the present application is not bound by the decision referenced and quoted above; however, Applicants should be entitled to a basic consistency from the Patent Office when interpreting Michal, et al.

As such, Applicants respectfully submit that independent claim 23 is patentable over Michal, et al., either alone or in any combination. Applicants also respectfully submit that for at least the reasons indicated above relating to the corresponding independent claim, the pending dependent claims patentably define over the references cited. However, Applicants also note that the patentability of the dependent claims certainly does not hinge on the patentability of the independent claim. In particular, it is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claim.

Applicants respectfully submit that the presently pending application is in complete condition for allowance. However, Examiner Zacharia is invited and encouraged to contact the undersigned should any further questions or concerns arise after consideration of this response.

Respectfully submitted,
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Date



The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CAMERON ROUNS
and JAMES PERRAULT

MAILED

MAY 16 2006

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 2006-0817
Application 10/325,443

ON BRIEF

Before WARREN, TIMM and JEFFREY T. SMITH, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

Decision on Appeal

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner finally rejecting claims 1 through 4 and 6 through 35, all of the claims in the application.

Claim 1 illustrates appellants' invention of a process for applying a lubricious coating to a surface of a medical device, and is representative of the claims on appeal:

1. A process for applying a lubricious coating to a surface of a medical device comprising:

providing a medical device made from a polymer;

contacting a surface of the medical device with a solvent and a multi-functional monomer, the solvent causing the surface of the medical device to swell and/or partially dissolve allowing the multi-functional monomer to be imbibed into the surface of the medical device;

drying the surface of the medical device; and

providing and polymerizing a polymer on the surface of the medical device, the polymer reacting with the multi-functional monomer imbibed into the surface of the device to form a lubricious coating.

The references relied on by the examiner are:

Michal et al. (Michal '285)	6,287,285	Sep. 11, 2001
Michal et al. (Michal '517)	6,656,517	Dec. 2, 2003
		(filed Jul. 25, 2001)

The examiner has provisionally rejected appealed claims 1 through 4 and 6 through 35 under the judicially created doctrine of obviousness-type double patenting over claims 1 through 50 of copending United States Patent Application 10/705,751, filed November 10, 2003 (answer, pages 3-4 and 8), and has rejected appealed claims 1 through 4 and 6 through 35 under 35 U.S.C. § 103(a) as being unpatentable over Michal '285 or '517 (answer, pages 4-7).

Appellants argue claims 1 through 4, 6 through 17 and 27 through 35 as a group and claims 18 through 26 as a group (brief, pages 5-7). We decide this appeal based on appealed claims 1, 2, 11, 12, 18 and 27 as representative of the grounds of rejection and appellants' groupings of claims. 37 CFR § 41.37(c)(1)(vii) (September 2004).

We affirm the provisional ground of rejection under the judicially created doctrine of obviousness-type double patenting and the rejection of claim 1 under § 103(a), and reverse the ground of rejection of claims 2 through 4 and 6 through 35 under § 103(a).

Accordingly, the decision of the examiner is affirmed.

Rather than reiterate the respective positions advanced by the examiner and appellants, we refer to the answer and to the brief and reply brief for a complete exposition thereof.

Opinion

We summarily affirm the provisional ground of rejection under the judicially created doctrine of obviousness-type double patenting because appellants state the intention to file a terminal disclaimer to obviate this ground, as acknowledged by the examiner (brief, pages 1-2 n.1; answer, page 8).

In order to consider the ground of rejection of representative claims 1, 2, 11, 12, 18 and 27 under § 103(a), we first interpret the language of the claims by giving the terms thereof the broadest reasonable interpretation in their ordinary usage in context as they would be understood by one of ordinary skill in the art in light of the written description in the specification unless

another meaning is intended by appellants as established in the written description of the specification, and without reading into the claims any limitation or particular embodiment disclosed in the specification. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004); *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

The terms of claim 1 encompass any process for applying a lubricious coating to any polymeric surface of any medical device comprising at least the steps, among others, of (1) contacting the polymeric surface with any manner of “multi-functional monomer” and any manner of solvent, wherein the solvent must cause the polymeric surface to swell and/or partially dissolve to any extent, however small, such that the “multi-functional monomer” is “imbibed into the surface” to any extent, however small; and (2) “providing and polymerizing a polymer” on the polymeric surface, wherein the polymer is any polymer in any amount, however small, which reacts “with the multi-functional monomer imbibed into the surface . . . to form” any manner of “lubricious coating.” The transitional term “comprising” opens the claim to include processes involving any manner of additional steps, reactants and reagents. *See, e.g., In re Baxter*, 656 F.2d 679, 686-87, 210 USPQ 795, 802-03 (CCPA 1981) (“As long as one of the monomers in the reaction is propylene, any other monomer may be present, because the term ‘comprises’ permits the *inclusion* of other steps, elements, or materials.”).

Appellants state in the written description in the specification that “[a]s used herein, the term ‘imbibing’ means that the multi-functional monomer is either chemically or mechanically bonded to a polymeric surface. Further, the term ‘monomer’ means any material capable of polymerizing or cross-linking with a polymer and can include monomers, oligomers, polymers, and the like” (page 4, ll. 22-26).

In view of these definitions stated by appellants, we interpret independent claim 1 as requiring that the solvent interact with the polymeric surface, which interaction can be visually determined by detecting swelling or dissolving of the surface, such that the multi-functional “monomer” is “imbibed,” that is, bonded by any chemical or mechanical interactions to the polymeric surface. The bonded multifunctional “monomer” can be any material that is capable

of polymerizing or cross-linking, that is, linking with another polymer which is provided to or formed on the “monomer” modified polymeric surface in order to form any manner of “lubricious coating.” Thus, the coating must be polymeric and have the property of being “lubricious” to any extent, however small, in which “lubricious” has its common, ordinary meaning in the context of the disclosure in the written description in the specification of having the property of being slippery or smooth.¹

The plain language of dependent claim 2 requires that the polymer reacting with the monomer to form the lubricious coating “is a hydrogel polymer,” wherein the hydrogel polymer can be polymerized on the surface, such as from quaternary amine acrylate monomers, as specified in dependent claim 1. The resulting hydrogel quaternary amine acrylate polymer, as specified in independent claim 18, can have more than 50,000 repeating units, as specified in dependent claim 12 and independent claim 27.

We agree with appellants that the Michal references “have substantially identical disclosures, except for the claims” (brief, page 2), and accordingly, we consider only Michal ‘285, applicable to the appealed claims under 35 U.S.C. § 102(b), as indeed, the examiner does not distinguish between the references. *See In re Jones*, 958 F.2d 347, 349, 21 USPQ2d 1941, 1942 (Fed. Cir. 1992); *In re Kronig*, 539 F.2d 1300, 1302-04, 190 USPQ 425, 426-28 (CCPA 1976).

We find that Michal ‘285 would have disclosed to one of ordinary skill in this art a lubricious, hydrophilic coating composition comprising, among others, a grafting component and a hydrophilic polymer, but not a binding component (e.g., col. 4, ll. 66-67, col. 5, ll. 9-14 and 48-51, and col. 17, Example 5). The grafting component adheres or grafts to the polymeric surface of the medical device and crosslinks to the hydrophilic polymer to form the lubricious, hydrophilic coating (e.g., col. 5, ll. 14-42, col. 11, ll. 16-45 and FIG. 5, and col. 17, Example 5). The grafting component includes various oligomers and polymers, is multifunctional and can interact with UV photoinitiators to polymerize and crosslink (e.g., col. 6, ll. 54-64, col. 19, l. 56, to col. 11, l. 15, col. 11, ll. 16-45 and FIG. 5, and col. 17, Example 5; *see answer*, page 4). The

¹ See generally, *The American Heritage Dictionary Of The English Language* 1038 (4th ed., Boston, Houghton Mifflin Company. 2000).

lubricious, hydrophilic polymer can be selected from a variety of polymers (e.g., col. 7, ll. 45-53, col. 11, ll. 36-45 and FIG. 5, and col. 17, Example 5). The compositions include suitable solvents, including alcohols and ketones (e.g., col. 13, ll. 21-23, and col. 17, Example 5).

In comparing the teachings of Michal '285 with appealed claim 1, we find that this reference would have taught each and every step of the process of claim 1 to one of ordinary skill in this art, such that this person reasonably following the teachings of the reference would indeed arrive at the claimed method encompassed by the claim, including each and every limitation thereof arranged as required therein, without resort to appellants' disclosure. *See generally, Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807, 10 USPQ2d 1843, 1845-46 (Fed. Cir. 1989). Furthermore, while the ground of rejection is under § 103(a), as a matter of fact, Michal '285 Example 5 satisfies all of the limitations of claim 1, establishing that claimed processes encompassed by this claim, as we have interpreted it above, lack novelty. It is well settled that "anticipation is the ultimate of obviousness." *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1284-85 (Fed Cir. 1991), citing *In re Fracalossi*, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982).

In view of these teachings of Michal '285, we cannot agree with appellants that the reference requires a binding component (brief, e.g., page 4). We also do not agree with appellants that the solvents used in the coating compositions of the reference that we found above do not perform the "imbibed" function specified in claim 1 (brief, pages 4-5 and 6-7). Indeed, Michal '285 performs the same steps using the same components and achieves the same result specified in the claimed process encompassed by claim 1, as we have interpreted this claim above. It is well settled that appellants' elucidation of the mechanism of an old process or discovery of a new benefit of that process does not render the old process again patentable simply because those practicing the process may not have appreciated the mechanism or the results produced thereby. *See, e.g., In re Spada*, 911 F.2d 705, 707, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983) ("[I]t is . . . irrelevant that those using the invention may not have appreciated the results[,] . . .

[otherwise] it would be possible to obtain a patent for an old and unchanged process. [Citations omitted.]"); *In re Skoner*, 517 F.2d 947, 950, 186 USPQ 80, 83 (CCPA 1975).

Furthermore, appellants have not established by effective argument or objective evidence that they have obtained a different result than the reference using the same solvents and the same materials in the same manner. *See, e.g., In re Best*, 562 F.2d 1252, 1255-56, 195 USPQ 430, 433-34 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. *See In re Ludtke* [441 F.2d 660, 169 USPQ 563 (CCPA 1971)]. Whether the rejection is based on "inherency" under 35 USC § 102, on "prima facie obviousness" under 35 USC § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. [Footnote and citation omitted.]"); *Skoner*, 517 F.2d at 950-51, 186 USPQ at 82-83; *see also In re Sussman*, 141 F.2d 267, 269-70, 60 USPQ 538, 541 (CCPA 1944) ("If appellant obtains a new product through reaction of the elements mentioned, it must be due to some step in the process not included in the claim."). Otherwise, to the extent that Michal '285 Example 5 anticipates claim 1, the case of obviousness on this basis cannot be rebutted with evidence. *Fracalossi*, 681 F.2d at 794, 215 USPQ at 571.

Accordingly, based on our consideration of the totality of the record before us, we have weighed the evidence of obviousness found in the Michal references with appellants' countervailing evidence of and argument for nonobviousness in the brief and reply brief, and based thereon, conclude that the claimed invention encompassed by appealed claim 1 would have been obvious as a matter of law under 35 U.S.C. § 103(a). *See generally, In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

We do not reach the same conclusion with respect to appealed claims 2 through 4 and 6 through 35. These claims require at least a hydrogel polymer with a number of claims requiring a quaternary amine acrylate polymer or, more specifically, such a polymer with greater than

50,000 repeating units, as we have interpreted the representative claims 2, 11, 12, 18 and 27 above.

The examiner fails to find in Michal '285 a hydrogel polymer, but reasons that the "amino functional acrylate groups (see appellants, claim 11 [sic, claim 12])" of the depicted formula "would correspond to the amine monomers of the acrylates of the type taught in Michal (2-aminoethyl methacrylate)," which when "treated with an acid the amine group would be protonated and thus form the neutralized salt thereof" in "[a]cid body fluids," resulting in "the quaternary amine structure" (answer, pages 4-5). In response to appellants' arguments (brief, page 7), the examiner contends that "[t]here will always be some degree of protonation" (answer, page 7).

The sole applicable disclosure of "2-aminoethyl methacrylate" in Michal '285 is with respect to the embodiment at col. 7, l. 57, to col. 8, l. 13, particularly, col. 8, l. 2. In this disclosure, the material is described as "a (co)monomer" for a hydrophilic agent top coat. However, this is in the context of "the binding component comprises an aldehyde compound and the top coat is a compound having amine groups" (col. 7, ll. 57-59). We find that one of ordinary skill in this art would have recognized from this embodiment that the reaction of the amine and aldehyde functional groups would result in imine moieties, as is well known in the organic chemistry arts,² which moieties in the disclosure of Michal '285 crosslink the binding component and the polymeric top coat (*see also* col. 6, l. 65, to col. 7, l. 3).

Thus, even if a number of amino groups remain unreacted in the polymeric top coat and may be protonated as the examiner finds, there is no showing on this record that the same would result in a hydrogel polymer and certainly not a hydrogel quaternary amine acrylate polymer, particularly one having more than 50,000 repeating units, as the examiner contends.

Accordingly, in the absence of a *prima facie* case of obviousness, we reverse the ground of rejection of appealed claims 2 through 4 and 6 through 35 under 35 U.S.C. § 103(a) over the Michal references.

² See, e.g., Romeo B. Wagner and Harry D. Zook, "Imines," "Method 465. Condensation of Carbonyl Compounds with Amines," *Synthetic Organic Chemistry* 728 (New York. John Wiley & Sons, Inc. 1953) (copy not provided).

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (2005).

AFFIRMED



CHARLES F. WARREN
Administrative Patent Judge

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CATHERINE TIMM
Administrative Patent Judge

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BOARD OF PATENT
APPEALS AND
INTERFERENCES


JEFFREY T. SMITH
Administrative Patent Judge

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Appeal No. 2006-0817
Application 10/325,443

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